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In re Application of <u>Platz</u>		
Application Number <u>08/246,034</u>		Filed <u>5/18/94</u>
Group	Art Unit	Examiner

Paper No. #13

Assistant Commissioner for Patents  
Washington, DC 20231

I hereby request access under 37 CFR 1.14(a)(3)(iv) to the application file record of the above-identified ABANDONED application, which is: (CHECK ONE)

- \_\_\_ (A) referred to in United States Patent Number 6,123,936, column \_\_\_\_\_,
- \_\_\_ (B) referred to in an application that is open to public inspection as set forth in 37 CFR 1.11, i.e., Application No. \_\_\_\_\_, filed \_\_\_\_\_, on page \_\_\_\_\_ of paper number \_\_\_\_\_,
- \_\_\_ (C) an application that claims the benefit of the filing date of an application that is open to public inspection, i.e., Application No. \_\_\_\_\_, filed \_\_\_\_\_, or
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#13

**United States Patent** [19]

Platz et al.

[11] **Patent Number:** **6,123,936**[45] **Date of Patent:** **Sep. 26, 2000**

[54] **METHODS AND COMPOSITIONS FOR THE DRY POWDER FORMULATION OF INTERFERONS**

[75] **Inventors:** Robert M. Platz, Half Moon Bay, Calif.; Shigenobu Kimura, Hyogo; Yu-ichiro Satoh, Sapporo, both of Japan; Linda C. Foster, Mountain View, Calif.

[73] **Assignee:** Inhale Therapeutics Systems, Inc., San Carlos, Calif.

[21] **Appl. No.:** 09/444,116

[22] **Filed:** Nov. 22, 1999

**Related U.S. Application Data**

[63] Continuation of application No. 08/737,724, filed as application No. PCT/US95/06008, May 15, 1995, which is a continuation-in-part of application No. 08/246,034, May 18, 1994, abandoned.

[51] **Int. Cl.<sup>7</sup>** ..... A61K 38/21; C07K 1/36

[52] **U.S. Cl.** ..... 424/85.6; 530/351; 514/2; 435/70.1; 424/43; 424/46; 424/489; 424/491

[58] **Field of Search** ..... 424/85.6, 85.4, 424/43, 46, 489, 491; 530/351, 363; 514/2, 21; 435/70.1; 128/200.14, 200.33

[56] **References Cited**

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[57] **ABSTRACT**

According to the present invention, methods and compositions are provided for spray-dried, interferon-based dry powder compositions, particularly interferon-beta. The compositions are useful for treating conditions in humans that are responsive to treatment with interferons. In particular, the methods of the present invention rely on spray drying to produce stable, high-potency dry powder formulations of interferons, including but not limited to IFN-beta. Surprisingly, it has been found that IFN can be prepared in high potency, dry powder formulations by spray drying. Such dry powder formulations find particular utility in the pulmonary delivery of IFN.

**22 Claims, No Drawings**